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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	23

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/425,633	Applicant(s) CHEE ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-26,29-31 and 42-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26,29-31 and 42-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 May 2002 has been entered.

2. This action is in response to papers filed 6 May 2002 in Paper No. 22 in which claims 23-26 and 29-31 were amended, claims 17-22, 27, 28 and 32-41 were canceled and claims 42-45 and 47-50 were added. Claims 47-50 have been renumbered 46-49 according to 37 C.F.R. 1.126. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 14 dated 2 May 2001 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejection and new grounds for rejection. The Declaration and Exhibits filed in Paper No. 22 have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Currently claims 23-26, 29-31 and 42-49 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-25, 45 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 23-25 are each indefinite for the recitation "said detectable label" because the recitation lacks proper antecedent basis in Claim 42. It is suggested that Claims 23-25 each be amended to provide proper antecedent basis.

b. Claim 45 is indefinite for the recitation "said capture probe ... serves as said first ligation probe" because "serves" is a non-descriptive function and therefore it is unclear functional limitation is being claimed. It is suggested that Claim 45 be amended to clarify e.g. replace "serves as" with "is".

c. Claim 47 is indefinite for the recitation "said capture probe is a protein" because it is unclear how the protein hybridizes to a sequence of the ligation product as required in Claim 42. It is suggested that Claim 47 be amended to clarify.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 23-26, 30, 31 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nikiforov et al (U.S. Patent No. 5,952,174, issued 14 September 1999) in view of Weisburg et al (U.S. Patent No. 6,110,678, issued 29 August 2000).

Regarding Claim 42, Nikiforov et al teach a method of determining the identification of a nucleotide at a detection position in a target sequence comprising: providing a hybridization complex comprising a) a first target sequence comprising a first nucleotide at a detection position; a first target domain directly 5' adjacent to said detection position; and a second target domain 3' adjacent to said detection position; b) a first ligation probe hybridized to said first target domain; and c) a second ligation probe hybridized to said second target domain; contacting said hybridization complex with an extension enzyme and at least one dNTP such that if the base of said dNTP is complementary to the base of said detection position, said first ligation probe is extended to form a ligation structure; contacting said ligation structure with a ligase to ligate said extended ligation probe and said second ligation probe to form a ligation product; and detecting the presence of said ligation product to identify the nucleotide at said detection position (Claim 1), said detection comprising providing a substrate with a surface comprising discrete sites and a capture probe i.e. a preferred 96-well microtiter plate (Column 10, line 63-Column 11, line 4 and Fig. 4) and they teach capture probes which hybridize to the ligation product (i.e. the first ligation probe is the capture probe) but they do not teach the discrete sites comprise microspheres comprising capture probes which hybridize to the ligation product. However, surfaces comprising microspheres comprising capture probes were well known in the art at the time the claimed invention was made as taught by Weisburg et al (Column 14, lines 58-67). Weisburg et al teach a similar method of determining a target comprising the steps of providing a hybridization complex comprising a) a first target sequence comprising a detection position; a first target domain 5' adjacent to said detection position; and a second target domain 3' adjacent to said detection position; b) a first probe hybridized to said first target domain; and c) a second probe hybridized to said second target domain; contacting

said hybridization complex with an extension enzyme and at least one dNTP such that said first probe is extended to form product; and detecting the presence of said product to identify the nucleotide at said detection position said detection comprising providing a substrate further comprising microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a capture probe which hybridizes to a sequence within said product (Column 11, lines 26-58 and Fig. 3) wherein their capture probe hybridization permits target-probe hybridization and target-capture probe hybridization to occur under different environmental conditions which permits optimization of both hybridization environment and capture environment (Column 4, line 57-Column 5, line 19) and wherein the capture probe hybridization of Weisburg et al optimizes environmental conditions for numerous methods e.g. primer extension and ligation (Column 7, lines 35-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capture of Nikiforov et al by providing microspheres having capture probes which hybridize to the extension product as taught by Weisburg et al to thereby optimize environmental conditions for each method step (i.e. hybridization, primer extension, ligation and capture) as suggested by Weisburg et al (Column 4, lines 57-Column 5, line 19) for the obvious benefits of maximizing experimental results.

Regarding Claim 23, Nikiforov et al teach the method wherein a detectable label comprises a fluorophore (Column 13, lines 28-36).

Regarding Claim 24, Nikiforov et al teach the method wherein a detectable label comprises a biotin (Column 13, lines 28-36).

Regarding Claim 25, Nikiforov et al. teach the method of wherein said label is a hapten e.g. biotin (Column 13, lines 28-36) but they do not teach the hapten comprises imine-biotin However, haptens comprising imine-biotin were known and routinely practiced in the art at the time the claimed invention was made and it was well known that imine-biotin and biotin are functionally equivalent labels. The courts have stated with regard to chemical homologs that

the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the biotin label of Nikiforov et al. with functional equivalent and routinely practiced imine-biotin based on their equivalent functionality for the and based on available reagents and equipment and for the benefit of convenience and economy.

Regarding Claim 26, Nikiforov et al teach the method wherein the dNTP comprises a functional group for the addition of a fluorophore i.e. biotin hapten (Column 13, lines 28-36 and Fig. 4, step 5.).

Regarding Claim 30, Nikiforov et al teach the method wherein the substrate is selected from the group consisting of glass and plastic (Column 10, line 63-Column 11,line 4).

Regarding Claim 31, Nikiforov et al teach the method wherein a detectable label is a fluorophore (Column 13, lines 28-36).

Regarding Claim 43, Nikiforov et al teach the method wherein said ligation probe is captured by the solid support (Column 13, lines 21-24 and Fig. 4) but they do not specifically teach the ligation probe comprises an adapter sequence that hybridizes to said capture probe. However, Weisburg et al teach the similar method wherein said probe comprises an adapter sequence that hybridizes to said capture probe (Column 4, lines 23-35 and Fig 3) wherein their capture probe hybridization permits target-probe hybridization and target-capture probe hybridization to occur under different environmental conditions and therefore permits optimization of both hybridization and capture (Column 4, line 57-Column 5, line 19) and wherein the capture probe hybridization of Weisburg et al optimizes numerous methods e.g. primer extension and ligation (Column 7, lines 35-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capture of Nikiforov et al by providing microspheres having capture probes which hybridize to the

extension product as taught by Weisburg et al to thereby optimize environmental conditions for the each method step (i.e. hybridization, primer extension, ligation and capture) as suggested by Weisburg et al (Column 4, lines 57-Column 5, line 19) for the obvious benefits of maximizing experimental results.

Regarding Claim 44, Nikiforov et al teach the method wherein said dNTP comprises a detectable label (Column 7, line 65-Column 8, line 9 and Fig. 4).

Regarding Claim 45, Nikiforov et al teach the method wherein the first ligation probe is the capture probe (Column 3, lines 38-42).

Regarding Claim 46 (47), Nikiforov et al teach the method wherein the capture probe is a nucleic acid (Column 3, lines 38-42).

Regarding Claim 47 (48), Nikiforov et al teach the method wherein the capture probe is a protein i.e. antibody (Fig. 4).

Regarding Claim 48 (49), Nikiforov et al teach the method wherein the discrete sites are wells (Column 10, lines 63-67).

7. Claims 29 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nikiforov et al (U.S. Patent No. 5,952,174, issued 14 September 1999) in view of Weisburg et al (U.S. Patent No. 6,110,678, issued 29 August 2000) as applied to Claim 42 above and further in view of Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998).

Regarding Claim 29, Nikiforov et al teach a method of determining the identification of a nucleotide at a detection position in a target sequence comprising: providing a hybridization complex comprising a) a first target sequence comprising a first nucleotide at a detection position; a first target domain directly 5' adjacent to said detection position; and a second target domain 3' adjacent to said detection position; b) a first ligation probe hybridized to said

first target domain; and c) a second ligation probe hybridized to said second target domain; contacting said hybridization complex with an extension enzyme and at least one dNTP such that if the base of said dNTP is complementary to the base of said detection position, said first ligation probe is extended to form a ligation structure; contacting said ligation structure with a ligase to ligate said extended ligation probe and said second ligation probe to form a ligation product; and detecting the presence of said ligation product to identify the nucleotide at said detection position (Claim 1), said detection comprising providing a substrate with a surface comprising discrete sites and a capture probe (Fig. 4) i.e. a preferred 96-well microtiter plate (Column 10, line 63-Column 11, line 4) and they teach capture probes which hybridized to the ligation product (i.e. the first ligation probe is the capture probe)(Column 14, lines 58-67) and . Weisburg et al teach a similar method of determining a target comprising the steps of providing a hybridization complex comprising a) a first target sequence comprising a detection position; a first target domain directly 5' adjacent to said detection position; and a second target domain 3' adjacent to said detection position; b) a first probe hybridized to said first target domain; and c) a second probe hybridized to said second target domain; contacting said hybridization complex with an extension enzyme and at least one dNTP such that said first probe is extended to form product; and detecting the presence of said product to identify the nucleotide at said detection position said detection comprising providing a substrate further comprising microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a capture probe which hybridizes to a sequence within said product (Column 11, lines 26-58 and Fig. 3) wherein their capture probe hybridization permits target-probe hybridization and target-capture probe hybridization to occur under different environmental conditions and therefore permits optimization of both hybridization and capture (Column 4, line 57-Column 5, line 19) and wherein the capture probe hybridization of Weisburg et al optimizes numerous methods e.g. primer extension and ligation (Column 7, lines 35-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify

the capture of Nikiforov et al by providing microspheres having capture probes which hybridize to the extension product as taught by Weisburg et al to thereby optimize environmental conditions for each method step (i.e. hybridization, primer extension, ligation and capture) as suggested by Weisburg et al (Column 4, lines 57-Column 5, line 19) for the obvious benefits of maximizing experimental results.

Nikiforov et al and Weisburg et al do not teach the substrate is a fiber optic bundle. However, fiber optic bundle substrates were well known in the art at the time the claimed invention was made as taught by Walt et al. who teach a similar method of target detection comprising providing a hybridization complex and detecting the complex to identify the target wherein the detection comprises providing a substrate with a surface comprising discrete sites, further comprising a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a capture probe and wherein the substrate is fiber optic bundle (Claim 17) wherein the fiber optic bundle substrate provides "extremely high density" substrate for detection of an extremely high number of targets (Column 5, lines 24-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the fiber optic substrate of Walt et al to the substrate of Nikiforov et al and Weisburg et al for the obvious benefits of detecting an extremely high number of targets using the same substrate as taught by Walt et al (Column 5, lines 24-31).

Regarding Claim 49 (50), Nikiforov et al teach the method wherein the target is randomly distributed i.e. 20 µl aliquots of the PCR mixture are placed in each well (Column 17, lines 20-30) and Weisburg et al teach their microspheres are magnetically i.e. non-specifically attracted to the support (Column 14, lines 64-67) but Nikiforov et al and Weisburg et al do not specifically teach microspheres are randomly distributed on a substrate. However, Walt et al who teach the similar method also teach randomly distributed microspheres (Claim 17) wherein the random distribution is faster and less expensive that other distribution methods

known in the art (Column 4, lines 53-56). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the random distribution of Walt et al to the substrate distribution of Nikiforov et al and Weisburg et al for the obvious benefits of speed and economy as taught by Walt et al (Column 4, lines 53-56).

Response to Applicant's Remarks and Declaration by Dr. Stueplnagel

8. Applicant's arguments regarding the previous rejections have been considered but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection detailed above.

Applicant cites the courts for having stated that objective evidence of nonobviousness (e.g. commercial success) must be taken into account before a conclusion of obviousness can be reached. And Applicant provides the following evidence of their commercial success:

A news release announcing an agreement between Applicant and Johns Hopkins Medical University in which Illumina (Applicant) will provide genotyping services on samples collected by Johns Hopkins.

A news release announcing an agreement between Applicant and Boston University Medical Center in which Illumina (Applicant) will provide genotyping services on samples collected by Boston University Medical Center.

A news release announcing an agreement between Applicant and University of California, San Diego in which Illumina (Applicant) will provide genotyping services on samples collected by the university's Laboratory of Psychiatric Genomics.

A news release and statement from the CEO of Oxagen announcing the agreement between Applicant and Oxagen in which Illumina (Applicant) will provide genotyping services on samples collected by the Oxagen.

Applicant argues that in view of the above evidence of commercial success and in view of the fact that neither Nikiforov et al, Walt et al, or Lyamichev et al individually teach every

element of the instantly claimed invention, a *prima facie* case of obviousness has not been established.

The arguments have been considered but are not found persuasive for numerous reasons. As stated above, new grounds for rejection necessitated by amendment clearly demonstrate that the instant invention is obvious in view of the teachings of Nikiforov et al and Weisburg et al (claims 23-26, 30, 31 and 42-48) and further in view of Walt et al (claims 29 and 49).

Regarding commercial success, Applicant's arguments and illustrations of commercial success are not deemed as sufficient evidence of nonobviousness because Applicant has not clearly established a nexus between the claimed invention and commercial success.

> An applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success (see MPEP, 716.03).
>
> The courts have stated that when considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. *In re Mageli*, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973) and *In re Noznick*, 478 F.2d 1260, 178 USPQ 43 (CCPA 1973).
>
> In ex parte proceedings before the Patent and Trademark Office, an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of nonobviousness is to be accorded substantial weight. See In re Huang, 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996) (Inventor's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus

> between the sales and the claimed invention.). Merely showing that there was commercial success of an article which embodied the invention is not sufficient. Ex parte Remark, 15 USPQ2d 1498, 1502-02 (Bd. Pat. App. & Inter. 1990).

As evidence of commercial success, Applicant has provided Exhibit B consisting of a copy of a brochure titled "Illumina's SNP Genotyping Services and Technology" and a copy of a 29 page Power Point presentation. The brochure is clearly used to promote the products and services of Illumina as evidenced by the last page which states "learn more by calling us at 1.800.809.4566 or visiting www.illumina.com/1snp." The Power Point presentation also provides evidence of advertising and/or promotion as it itemizes services provided and advantages of Illumina technology. As such, Exhibit B suggests that Applicant's commercial success may be the result of promotion and/or advertising.

As further evidence of commercial success, Applicant has provided Exhibit C consisting of 6 news releases regarding the agreements detailed above and a Declaration signed by John Stuelpnagel a co-inventor of the instant invention. Five of the six news releases are provided by Illumina on their "shareholder" web site. Each of the five news releases contains the same paragraph predicting the future of Illumina and providing the details for investing and contacting Illumina i.e. "Illumina (Nasdaq: ILMN; www.illumina.com) is developing next-generation tools....". As such, the news releases provide further evidence that Applicant's commercial success may be the result of promotion and/or advertising.

The Declaration provided by Dr. Stuelpnagel reiterates the above listed agreements and states that the agreements utilize methods comprising ligation and extension assays and thus "utilize methods outlined in the claims". Dr. Stuelpnagel further declares that the "high throughput, cost-effectiveness, accuracy and flexibility of this system, as embodied by the claims are directly responsible for its [Illumina's] commercial success." Dr. Stuelpnagel's Declaration has been considered but is not found persuasive because the Declaration suggests

that Illumina utilizes methods embodied by the claims, the Declaration does not provide evidence that the products sold correspond to the claimed invention. Therefore, the Declaration does not provide the nexus between the claimed invention and Applicant's commercial success.

> An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language **does not establish a nexus between the claimed invention and the commercial success** because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. Ex parte Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988).

Applicant's arguments regarding their commercial success being evidence of nonobviousness is not found persuasive because Applicant's exhibits provide multiple examples of advertising and promotion which suggests that Applicant's commercial success may be a result of the illustrated advertising and promotion and because Applicant's exhibits and Declaration do not provide a nexus between the claimed invention and commercial success. Therefore, Applicant has not shown that the features of the instantly claimed invention is responsible for Illumina's commercial success.

Conclusion

9. No claim is allowed.

10. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 19, 2002